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DIPLOMATE OF THE AMERICAN BOARD OF INTERNAL MEDICINE
AND IN THE SUBSPECIALTY OF GASTROENTEROLOGY

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IRA SHAFRAN, M.D.
LYNN J. KUGLER, P.A.-C.

November 14, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Refer to Docket number 00p-1499/CP1

Dear FDA,

Please be advised that I have used Lotronex successfully and safely in over twenty patients. We have seen no adverse effects with this drug, which has been of great benefit to our patients with irritable bowel syndrome. I do think it will have multiple applications, off labeled, for other diarrhea conditions and will be of benefit. I do feel that further study is warranted to test the safety and efficacy of this product in a larger number of males and females to determine the real risk of ischemic bowel.

Should you have any questions please contact us.

Sincerely,



Ira Shafran, M.D.

IS/jhc

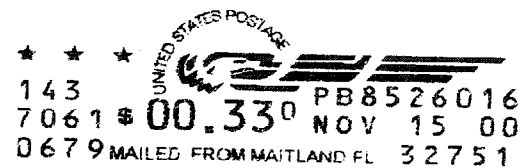
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